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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,108	01/25/2002	Geert Plactinck	D00590.70011.US	1549
23628 7590 07/03/2007 WOLF GREENFIELD & SACKS, P.C. 600 ATLANTIC AVENUE BOSTON, MA 02210-2206			EXAMINER SINGH, ANOOP KUMAR	
			ART UNIT 1632	PAPER NUMBER
			MAIL DATE 07/03/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/057,108

Applicant(s)

PLAETINCK ET AL.

Examiner

Anoop Singh

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☒ Certified copies of the priority documents have been received in Application No. 09/347311.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

The Examiner prosecuting this application has been changed. Any inquiries relating to the examination of the application should be directed to Examiner Singh. The telephone number is provided at the end of this office action.

Applicants' amendment and response filed March 16, 2007 has been received and entered. Claims 1-12 and 30-53 have been cancelled. Claims 13-29 are pending in this application.

Election/Restrictions

As indicated before Groups I-III were rejoined. Claim 13-29 remain currently under examination as they are drawn to a micro-organism comprising an expression vector that when expressed produces double stranded RNA and to use of said product in a method for reducing the expression of a gene of interest in *C. elegans*.

Maintained- Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 13-29 remain rejected under 35 U.S.C. 102(a) as anticipated by Timmons and Fire (East Coast Worm meeting, abstract, May 12, 1998, art of record) as evidenced by Fire et al (Nature 391, 80, 1998, art of record).

Timmons and Fire et al disclose a method of down-regulating gene expression in *C. elegans* by allowing to feed on bacteria that produces a double stranded RNA. The

bacteria strain used was BL21/DE3 and had alternative promoters for expression of the dsRNA, the Lac and T7 polymerase promoters.

Accordingly, Timmons anticipates claims 13-29.

Response to Arguments

As an initial matter it is noted that applicants have correctly indicated that Examiner had inadvertently rejected claims 13-29 under 102(e) as it was meant to be a rejection under 35 USC § 102(a), particularly since neither of references were US Patent. Since both are 102 type rejection and do not change the basic ground of the rejection, hence rejection of claims 13-29 are maintained for the reasons of record.

Applicant's arguments filed March 16, 2007 have been fully considered but they are not fully persuasive. Applicants argue that the Fire et al. Nature article, relied upon by the Examiner to evidence a variety of elements of Applicant's claimed invention that allegedly are described in the Timmons and Fire meeting abstract, in fact does not refer to feeding of dsRNA. Applicants further assert that Fire et al. Nature article does not teach or evidence feeding of bacteria, the use of T7 promoter for expression of RNA, or the use of Lac promoter for expression of RNA. The Nature article only describes microinjection of RNA, which is entirely different than feeding on bacteria expressing dsRNA. Applicants claim that lack or description of the elements of Applicant's invention as claimed, the Fire et al. Nature article would not be viewed by the person of skill in the art as relevant for evidencing aspects of Applicant's invention alleged by the Examiner to be taught by the Timmons and Fire meeting abstract. Therefore, the prior art does not anticipate the claimed invention.

In response, it is noted that claim 13 is directed to a method for down regulating the expression of a gene of interest in *C.elegan* by feeding *C.elegan* with a microorganism that expresses dsRNA corresponding to gene of interest. As written, claim only requires one method step that is feeding *C.elegan* with any microorganism that expresses ds RNA. In fact there is no requirement that such feeding results in down regulation of the expression of gene of interest. Furthermore, In the instant case, the

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abstract cited by examiner (Timmons and Fire, May 12, 1998) teaches bacteria expressing GFP or unc-22 were fed to myo3:GFP worm (see para. 2). It is noted that a reduction in muscle cell GFP expression was observed in animal fed with bacteria expressing dsGFP RNA (see para. 2 of the abstract). In response to applicant's arguments against the references of Fire et al individually, it is emphasized that Examiner had cited the references of Fire et al only as an evidence that variety of elements of Applicant's claimed invention that are described in the Fire et al nature article are the same as one disclosed by Timmons and Fire (meeting abstract) to observe specific RNAi effect in worm that have ingested dsRNA (see para. 3 of the abstract). It is noted that Timmons et al specifically cite the reference of Fire Nature article that uses bacteria strain BL21/DE3, including the use of T7 promoter for expression of RNA, or the use of Lac promoter for expression of RNA to describe feature of RNAi technology and contemplated if dsRNA was delivered to the gut via feeding the worm with bacteria that express dsRNA. Thus, it is apparent that Timmons and Fire clearly show that RNAi phenomena observed in *C.elegans* after injecting dsRNA into a body cavity or gut (as evidenced by Fire et al Nature article 1998) could be achieved by feeding the worms with bacteria expressing dsRNA (see para. 2-4 of the abstract). In addition, it appears that this abstract resulted in publication (Timmons et al Nature, 395, 1998, art of record) teaching that the bacteria expressing the dsRNA can be used to express any gene of interest and provided to *C. elegans* as a food source wherein the expression of the dsRNA results in the down regulation of the gene of interest in the *C. elegans*. In view of preceding analysis it is apparent that Timmons and Fire teach a method to observe a specific RNAi effect in *C. elegans* that have ingested dsRNA via feeding the worm that expresses dsRNA.

Conclusion

No claims allowed.

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THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anoop Singh whose telephone number is (571) 272-3306. The examiner can normally be reached on 9:00AM-5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272- 4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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AU 1632

/Anne-Marie Falk/
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